UNITED STATES PATENT AND TRADEMARK OFFICE

C1C

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,256	09/23/2002	Roelof Van Hes	01975.0035	7664

22852 7590 10/21/2005

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
BERNHARDT, EMILY B	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,256	VAN HES ET AL.	
	Examiner	Art Unit	
	Emily Bernhardt	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,4-8* is/are allowed.

6)☒ Claim(s) *9* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/30/05 has been entered.

Claim 9 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The scope of claim 9 remains indeterminate for reasons previously provided. Applicants' traverse in their preliminary response is not persuasive. Applicants first stress that their compounds have a high affinity for the D2 receptor and the serotonin reuptake site yet the claim recites treating a "disorder....wherein...the disorder is caused by a disturbance in the dopaminergic or serotonergic systems". There are currently seven distinct families of 5-HT receptors that have been identified (5-HT1- 5HT7) and many subpopulations have been described and some cloned. There are at least 5 types of dopamine receptors and there is no reason to doubt that more types/subtypes will be discovered and studied and found to be usefult for one or more diseases. While applicants' compounds have a dual mode

of action which makes them useful for diseases known in art as evidenced by the references previously provided, there are **no** particular disorders recited in this claim in contrast to claims 7-8. The examiner has raised several issues why the claim is indefinite which have not been specifically addressed by applicants. It is not believed to be implausible as applicants seem to ignore that the scope of diseases covered could alter over time. This is confirmed by Jones, another article on 5-HT receptors who states at p.55, lower right column the following: "In this short review, we have looked at the disorders that benefit from 5-HT research **currently** and those that may benefit in the **future**."

In such a case how could scope be determined with certainty when it may turn out that all diseases may be affected by a "disturbance" in the dopaminergic or serotonergic systems in whole or in part. If a disease responds to a second drug but not a first, both of whom activate a 5HT receptors *in vitro*, can one really conclude that the disease falls within the claims? It may be the positive response to the second drug is the result of some other biological mechanism which the second drug possesses but not the first. It is quite common for drugs to work by many mechanisms. Thus how many drugs need to be tested before it can be concluded if a disease is mediated or not by this biological process ? The same can be said for the scope of mammalian hosts. One may observe a positive response employing an

instant compound for a particular disease in one host but not another. It is quite common for pharmaceuticals to work only with some people, not all, much less any and all mammalian species. With regard to knowing who is in need vs who is not, how can such be determined? One may have no visible symptoms and still be in need. It may turn out with further research that everyone is in need or that one only needs a specific type or subtype of serotonin receptor among the many types and subtypes that exist. Additionally exacerbating the scope is the term "disturbance" which could suggest that the dopaminergic or serotonergic system is indirectly responsible for a disorder and that alteration of said systems may allow the brain to compensate for some other problem underlying the cause of the disorder.

For all of the above reasons, determining the actual scope of such a claim will involve not only extensive but also potentially open-ended and inconclusive research which renders the claim rejected herein indefinite.

Claim 9 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection of the previous actions regarding the scope of uses

covered by the claim language remains for reasons of record. The references previously provided do not evidence that SSRI's or D2 agonists/antagonists are known for such a range of uses at the time of applicants' effective filing date. Applicants do not address much less refute these references. Also see Jones regarding the treatment of uses specifically described in the specification, namely aggression and cognition and memory. Reliance on the Cross v. Iizuka decision is misplaced as the issue therein was the sufficiency of disclosure to support a "practical utility" which is needed to satisfy 35 U.S.C. 101. There were no method claims involved in the Interference Count. More apt to the instant fact situation is Genentech vs. Novo Nordisk 42 USPQ 2d 1001 especially left column at p.1005 which states the following:"Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may be workable." . In the same decision at p.1004 it is clearly stated that "to be enabling the specification must teach ... how to make and use the full scope of the claimed invention without undue experimentation."

The terminal disclaimer filed by applicants to overcome the obviousness-type double patenting rejection over 10/432,225 has been approved by the PTO staff.

The abstract of the disclosure remains objected to for reasons of record. Correction is required. See MPEP § 608.01(b). While applicants have attempted to insert intended use(s) to the abstract the current amendment practice is to provide a new abstract incorporating the intended changes.

Claim 3 is objected to since the phrase "wherein X is the group...having formula(1)," is redundant in view of the narrowing of claim 1 to only one X choice. It should be deleted.

Claims 1,4-8 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

E Bernhardt

Emily Bernhardt
Primary Examiner
Art Unit 1624